Long Term Follow-up after Mitral Valve Repair in Patients with Severe Left Ventricular Dysfunction of Ischemic Etiology: Survival and Quality of Life

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INTRODUCTION

The mitral valve connects the left atrium to the left ventricle and consists of the annulus with its two leaflets. The average annulus cross-sectional area ranges from 5 to 11.4 cm^2 in a normal human heart. Both mitral leaflets are connected to chorda tendinea that again connect to the papillary muscles in the left ventricle. A sufficient valve prevents systolic leakage of blood to the atrium, and the papillary muscles contribute to apical movement of the annulus during systole, thus enhancing emptying of the left ventricle.

The term cardiomyopathy is used to describe heart disease resulting from a primary abnormality in the myocardium. Although the term ischemic cardiomyopathy has gained popularity among clinicians to describe chronic heart failure caused by coronary heart disease[1], the pathological diagnosis should be chronic ischemic heart disease.

In most instances, there has been a prior myocardial infarct, an unstable coronary syndrome or angina pectoris, and often these patients will show symptoms of generalized atherosclerotic disease. The non-infarcted viable myocardium usually undergoes both compensatory hypertrophy and dilatation. Wall tension increases, fibrosis follows and diastolic and systolic dysfunction develop. The patients then develops mitral regurgitation[2], first during ischemia; later the valve leakage becomes permanent. One effect of mitral regurgitation is reduced systemic blood flow (forward

failure). The backward mitral flow increases left atrial pressure, and the atrium dilates. Atrial wall stretch increases, predisposing to atrial fibrillation which adds further to the decompensation of the left side of the heart. Pressure and volume overload in the atrium leads to dilatation and hypertrophy, the contribution of each may vary. In the ventricle, remodelling is mainly expressed as dilatation, due to volume overload. The end-stage of this development is heart failure, and in advanced cases, pulmonary congestion and even of right sided heart failure (hepatomegali and peripheral edemas are severe signs).

The clinical symptoms and signs of mitral regurgitation is a systolic heart murmur with an apical or axillar point of maximum, weakness, fatigue, palpitations and dyspnoea. The patients are at increased risk for contracting bacterial endocarditis. The degree of heart failure is described by the New York Heart Association (NYHA)-classes I-IV.

In our study we followed a group of patients with severe ischemic cardiomyopathy with EF<25%, who underwent mitral valve repair. The natural history of these patients is very bad. Mortality has been reported to 31% within one year[3]. Those with congestive heart failure and mitral regurgitation have a life expectancy of less than 12 months[4]. Following acute MI, approximately 20% develop ischemic mitral regurgitation[5].

Mitral valve repair is beneficial for this group of patients and is, whenever possible, the treatment of choice. Mitral valve replacement is only performed if the valve cannot be repaired[6 7]. In many cases the patients would not survive the additional constraint of mitral valve replacement. Mitral valve repair results in a smaller pressure gradient across the valve, compared to an artificial valve, and an intact unit of chordae and papillary muscles contributes significantly to systolic work. The most severe cases would in the end be candidates for heart transplantation.

There have been several studies on short-term follow-up of similar patient groups, but not many on long-term. In addition to this physical follow-up we wanted to study the life quality of the surviving patients.

MATERIAL AND METHODS

Patients

This study was performed at the Sharee Zedek Medical Centre in Jerusalem, Israel, at the Cardiac Thoracic Surgery Department. We included all patients who underwent surgical mitral valve repair (MVr) for severe insufficiency due to ischemic cardiomyopathy, between 1996 and 2004. The follow-up was performed mainly between December 2004 and January 2005. The control group for SF-36 was the Urban Jewish Population between 45 and 75 years[8].

The preoperative patient data were retrieved from the hospital's journal/database. The regular follow-up of the patients is done every second year. The patients are called up at home, and an assistant (mainly a medical student under special supervision) asks questions about the patient's health and their complaints. Their NYHA functional class was derived from these data. If the last follow-up was more than 6 month ago, this was done by E.A or H.P.M during the investigation period. Some patients forwarded their files from other hospitals because of severe morbidity or difficulties with describing their medical condition.

All survivors were invited to an echocardiographic examination and a quality-of-life assessment (SF-36 questionnaire). If a patient had a deterioration of their echo-results since last follow-up, they were offered an appointment with a cardiologist. Patients who had a long travel to the hospital or poor fitness, had their echo examination done at their local hospital, and answered the SF-36 questionnaire at home. These patients received their questionnaire by mail or fax.

The short-form 36 (SF-36)

The SF-36 is a multi-purpose short-form health survey with 36 questions. The questionnaire consists of eight scales, to measure health; physical functioning (PF), social functioning (SF), role limitation attributed to physical problems (RLP), role limitation attributed to emotional problems (RLE), mental health (MH), energy/vitality (E/V), bodily pain (BP) and general health perception (GH). The answers of the 36 questions are divided into these 8 categories and transformed to give 8 scores between 0 and 100, with 0 being worst state, and 100 best. There are also two standardised summary scores that can be calculated from the SF-36; the physical component summary (PCS) and the mental health component summary (MCS). From the Israeli Ministry of Health we received the official translation of the SF-36 to Hebrew, which was used in the survey. The SF-36 values of the Urban Jewish Population between 45 and 75 years were used for comparison[8].

For the Hebrew and English-speaking patients the SF-36 was provided in their own language. The Arabic- and Russian-speaking patients brought with them a translator, usually a younger family member. The patients, who answered the SF-36 at the hospital, usually had an accompanying family member who could explain the questions when necessary. The questionnaires were analysed according to the "SF-36 Health Survey- Manual and Interpretation Guide"[9].

Echocardiography

The patients had a general echocardiographic examination performed by the technicians at the cardio lab. A cardiologist always reviews the taped video recording and corrects the results when necessary. We registered the ejection fraction (EF %) and the LVEDD (Left Ventricular End Diastolic Diameter). Preoperative measurements were retrieved from the hospital's database.

Survival data

Most of the mortality data were available in the hospital files/database.

Statistics

We analyzed the SF-36, the preoperative data and the follow-up data with SPSS or Excel data sheet. Student's t-test was used for comparison between groups. Survival data was analysed with the Kaplan-Meyer scale. The risk factors, immediate post-operative complications and the preoperative NYHA-class were analyzed with the Chi-square test. Because the low number of patients we used the continuity correction with 2-sided asymptomatic significance evaluation. For the analysis of NYHA development we looked at linear by linear association. The significance level was set at $p<0.05$.

RESULTS

Patients

The study consisted of 41 patients with severely compromised left ventricular function of ischemic aetiology, in which mitral valvuloplasty was performed. 88% were in NYHA functional-class III or IV at the time of surgery. 76% were men and 24% women, and their average age was 61.9 years. 38 patients had documented myocardial infarcts and in the remaining three, coronary angiography demonstrated a vascular cause of cardiomyopathy. 76 % had a mitral insufficiency of grade 4, 22 % had grade 3 and 2 % grade 2. Table 1 describes baseline data of the patients.

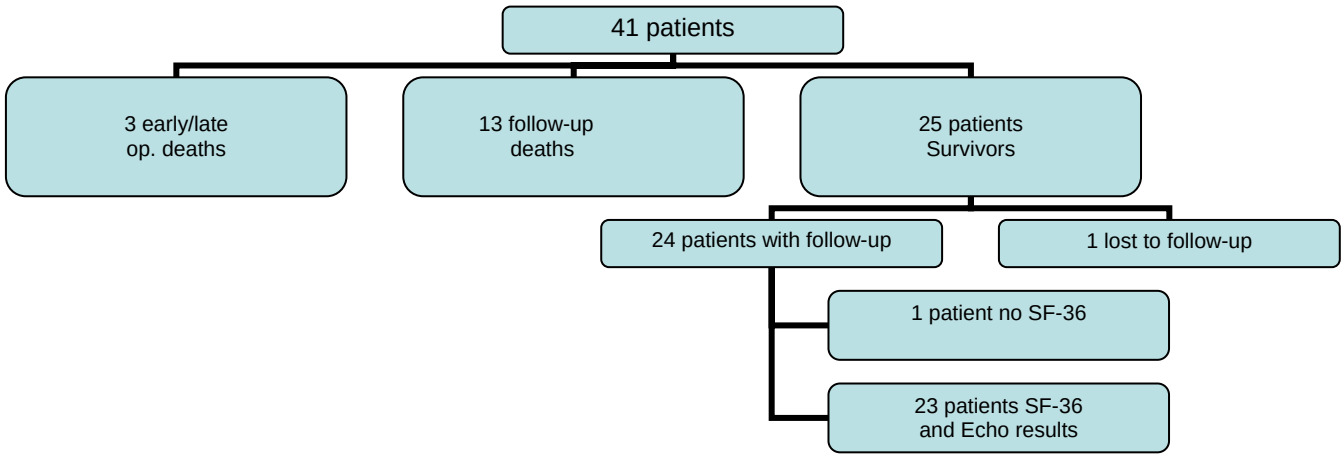
Table 1. Baseline data of the patients.

Category	**All patients (n=41)**
Female	24 % (n=10)
Male	76 % (n=31)
Age	61,9 (Range 45-82)
NYHA-class	3,65 (Range 1-4)
LVEDD (cm)	6,06 (Range 5,3-6,7)

NYHA - New York Heart Association functional class
LVEDD – Left Ventricular End Diastolic Diameter

The patients` main outcome are shown in Figure 1.

Figure 1. Patients` main outcome.



The category of operation of the patients is shown in Table 2a.

Table 2a.

Operative status	**All patients**	**Survivors**	**Non-survivors**
Elective (32 patients)	78 % (n=32)	84 % (n=21)	69 % (n=11)
Urgent (6 patients)	15 % (n=6)	8 % (n=2)	25 % (n=4)
Emergency (3 patients)	7 % (n=3)	8 % (n=2)	6 % (n=1)

All patients underwent mitral valve repair, and most of them also had additional coronary artery by-pass grafting (CABG) (95%), some of the patients had an additional valve repair or replacement (n=11). Their distribution is shown in Table 2b.

Table 2b.

Operation category	
CABG + MVr	71 % (n=29)
CABG+MVr+Other	20 % (n=8)
CABG+AVR+MVr+Other	2 % (n=1)
CABG+AVR+MVr	2 % (n=1)
MVr	2 % (n=1)
MVr + Other	2 % (n=1)

AVR- Aorta Valve Replacement

Their atherosclerotic and surgical risk factors are shown in Table 2c.

Table 2c Risk factors

RISK FACTORS	Starting point-group	Survivors	Non-survivors	p-value
Smoking	63 %	68 %	56 %	0,67
Diabetes	44 %	40 %	50 %	0,76
Hypertension	46 %	40 %	56 %	0,49
Hypercholesterolemia	54 %	48 %	63 %	0,56
Obesity	17 %	16 %	19 %	1,00
Cerebral Vascular Event	7 %	8 %	6 %	1,00
COPD	12 %	12 %	13 %	1,00
PVD	17 %	20 %	13 %	0,84
Pulmonary Hypertension	51 %	44 %	63 %	0,40
Renal failure	27 %	16 %	44 %	0,05
Endocarditis	2 %	4 %	0 %	1,00
Myocardial Infarction	93 %	88 %	100 %	0,41
Chronic Heart Failure	90 %	84 %	100 %	0,25
Atrial Fibrillation	15 %	4 %	31 %	0,05

COPD – Chronic Obstructive Pulmonary Disease

PVD – Pulmonal Ventricular Disease

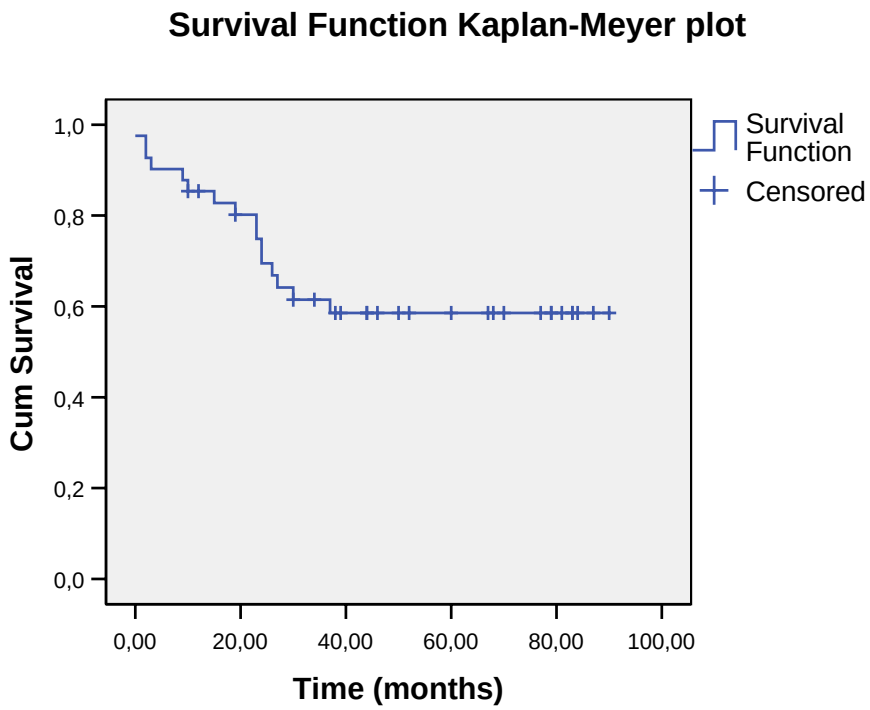
Follow-up

The follow-up time was from 34 to 90 months after surgery, in average 58 months. The follow-up was 96% complete: one patient refused to answer any questions due to bitterness towards the hospital because of blindness as a complication to the surgery. No patient in the study was lost to follow-up, although not all answered the questions. Both the SF-36 as well as the echo-follow-up-results were available in 92 % of patients.

Mortality

Mortality was 39 % (16 of 41 patients). During our follow-up calls we discovered a few deaths in addition to those registered in the hospitals files. In-hospital mortality was 7% (3 patients) and follow-up mortality was 32% (13 patients), in average death occurred 17 months after the initial operation. In 69 % the cause of death was cardiac and in 15 % cerebrovascular. Survival is illustrated with Kaplan-Meyer plot in Figure 3.

Figure 3. Kaplan-Meyer plot of survival.



Baseline differences are shown in table 2d.

Table 2d. Baseline differences between survivors and non-survivors.

Category	All patients	Non-survivors baseline	Survivors baseline	Survivors follow-up	P-value btw survivors b.l. and f.u.
Women	24 %	31 %	20 %		
Men	76 %	69 %	80 %		
Age Range (45-82)	62	65	60		
EF				31,9	
NYHA	3,7	4	3,4	2,2	0,02
LVEDD	6,1 (range 5,3-6,7)	5,8 (range 5,5-6,7)	6,2 (range 5,3-6,5)	6,1 (range 4,9-7,3)	0,50
NYHA IV		100% (n=16)	64% (n=16)		
NYHA III			16% (n=4)		
NYHA II			8%(n=2)		
NYHA I			8% (n=2)		

The immediate post-operative complications are shown in table 3

Table 3. Immediate post-operative complications

Complications	All patients	Survivors	Non-survivors	p-value
Atrial fibrillation	10 % (n=4)	12 % (n=3)	6 % (n=1)	0,95
Low cardiac output	56 % (n=23)	60 % (n=15)	50 % (n=8)	0,76
Sepsis	10 % (n=4)	4 % (n=1)	19 % (n=3)	0,31
Cerebral vascular incidence	10 % (n=4)	4 % (n=1)	19 % (n=3)	0,31
Perioperative myocardial infarction	5 % (n=2)	0 % (n=0)	13 % (n=2)	0,29
Renal failure	5 % (n=2)	0 % (n=0)	13 % (n=2)	0,29

Three of the patients were reoperated; in all cases mitral valve replacement was done.

We wanted to see the change of the NYHA-class from pre-operative to follow-up time. See table 4.

Table 4. In operative survivors, distribution of NYHA-classes preoperatively and at follow up.

NYHA-class	Preoperative Survivors	At follow up Survivors
NYHA IV	64% (n=16)	8% (n=2)
NYHA III	16% (n=4)	36% (n=9)
NYHA II	8%(n=2)	24% (n=6)
NYHA I	8% (n=2)	28%(n=7)

In one of the survivors we lack preoperative and postoperative NYHA classification.

SF-36 – Quality of life- assessment

The SF-36 was answered 92% of the survivors (23 of 25 survivors). See Table 5 for results.

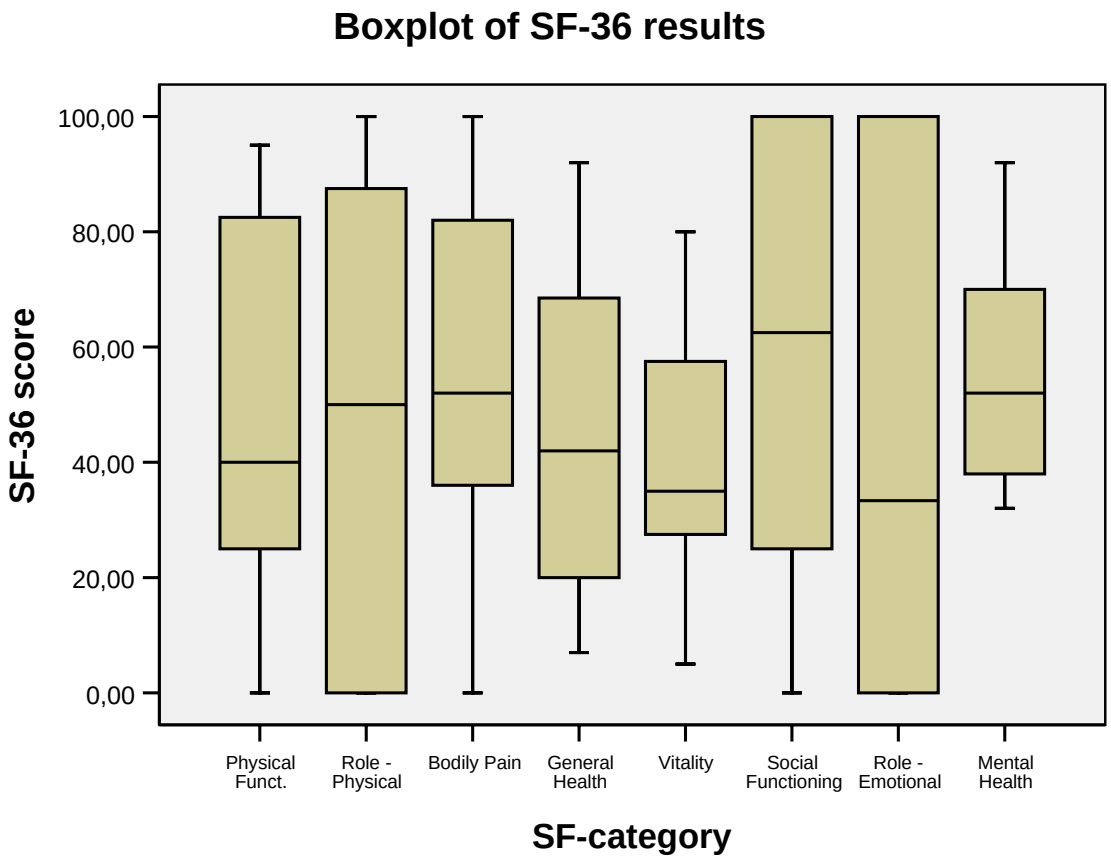
Table 5. SF-scores

SF-36 scale	Mean MVr (range)	Mean Control	CI MVr	CI Control	p-value
Physical functioning	50,65 (0-95)	78,28	36,92-64,39	77,23-79,32	<0,000
Role-Physical	46,73 (0-100)	68,46	28,33-65,15	66,77-70,14	0,012
Bodily Pain	58,69 (0-100)	69,38	46,27-71,12	68,22-70,55	0,073
General Health	45,52 (7-92)	63,55	34,35-56,69	62,62-64,48	<0,000
Vitality	43,04 (5-80)	56,73	33,83-52,26	55,8-57,66	0,004
Social Functioning	57,60 (0-100)	80,21	41,6-73,62	79,14-81,28	<0,000
Role-Emotional	52,17 (0-100)	77,18	33,05-71,3	75,59-78,78	0,002
Mental Health	52,17 (32-92)	67,32	47,9-63,75	66,45-68,2	0,010

CI=Confidence interval

Quality of life is significantly worse in patients for all categories, except for bodily pain. Borderline significance is seen for physical role and mental health. See Figure 4 for box plot of the SF-36 results. There is a large individual variation. This can be seen in the large range of the different parameters.

Figure 4 Box plot of SF-36. The figure illustrates the median, 25 and 75% percentile and range.

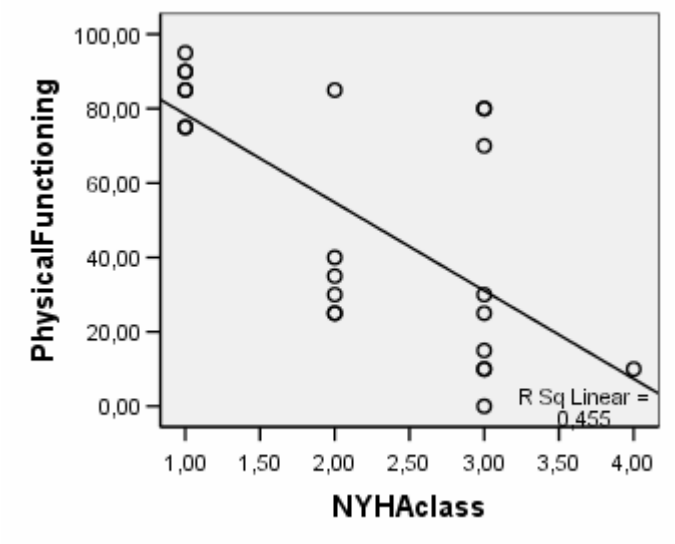


We calculated the SF-scores to physical component summary (PCS) and mental component summary (MCS) and got PCS score of 38.44 (15-57) and MCS score of 41.45 (22-60).

Physical role and the NYHA-class had a correlation coefficient (Pearson) of 0.37 (0.38 Spearman Correlation). The p-value was 0.82 (0.73 Spearman).

Physical functioning and the NYHA-class had a correlation coefficient (Pearson) of 0.67 (0.72 Spearman Correlation). p-<0.0001. See figure 5.

Figure 5. Correlation of physical functioning scores and NYHA-class.



DISCUSSION

The main findings of the present study are

1. We find a modest survival (61 % (25 of 41 patients)) in patients followed for up to 8 years after surgery.
2. The deaths were restricted to the patients with preoperative NYHA class IV.
3. The surviving patients had an acceptable quality of life at follow-up. Their NYHA-class and physical functioning scores correlated significantly.
4. Preoperative renal failure and atrial fibrillation were risk factors that significantly predicted death.

Survival

The follow-up was done in average 58 months after operation. We see from the Kaplan-Meyer plot that the deaths all occurred within the first 3 years. The patients who survive the 3 first years after surgery thus should be clinically stable with a good result of the treatment, and likely to survive for years. The preoperative NYHA-class for the survival-group was 3.4 preoperatively. The non-survivors all had NYHA-class 4 preoperatively. This was a significant difference with a p-value of 0.02 and shows that the patients with NYHA-class IV have a more severe prognosis. When we looked at the risk factors as a predictor for survival, renal failure and atrial fibrillation showed

significant p-values. This may be used in the preoperative evaluation of the patients. In the analysis of immediate post-operative complications we did not find any factor that was significant. Low EF is also reported to be a predictor[10], but in the present study we lack data on preoperative EF in many. In general, EF is useful for evaluation of chronic heart failure; however, the presence of mitral valve insufficiency reduces the value of EF to predict left ventricle contractility. An alternative measure is the LVEDD, and all patients had severe left ventricular dysfunction reflected by dilated left ventricular diameters preoperatively. The LVEDD did not change significantly.

In the period 1993-99, 21 patients with severe MI and ischemic cardiomyopathy received mitral valve repair at the same Israeli hospital. The report on these patients shows an excellent 3-year survival of 86% (3/21 died)[11]. The difference in survival is difficult to explain. One possible explanation could be that in the first study the mean follow up was only 13 months, compared to 58 months in our study. Although mitral valve surgery has been performed for many years, valve repair on patients with ischemic cardiomyopathy only started in the 90-ies[12]. The mortality of 63% after an average of 5.8 years is high, but not considering the gloomy prognosis of these patients had they not been operated upon. Although operation prolongs life-expectancy; it does not stop the progression of the heart disease. Bishay et al[13] show a similar group with a 2- and 5- year survival of 86 and 67%, respectively Bolling[14] showed 1- and 2- year survival of 80 and 70%.
Lee et al[15] showed that left ventricular dysfunction remains a major cause of mortality and morbidity following mitral valve repair. In contrast, renal failure on dialysis, stroke, no angina, age >65 yrs, absence of hypercholesterolemia, EF<26% but not 3/4+MR were independent predictors of "Initial late mortality"[16]. Working with almost the same material as our study is based on; Silberman et al showed that mitral valve repair offers a survival advantage as compared to replacement or no intervention on the valve[17].

Results of surgery in the survivor group

In our study we did not see a significant change in the LVEDD from preoperatively to follow-up. This is consistent with other findings[20], but there are also opposite results[18]. Despite this we see symptomatic improvements being reflected in the NYHA-class changes. The NYHA-class was average 2.2 at follow up. The average EF at follow-up was 31.9%. It gives us a picture of the surviving patients. Preoperatively they all had a dysfunctional myocardium. The contractility of myocard probably does not change so much after the operation, but because the repair of the mitral valve, the mitral insufficiency decreases, thus the efficiency increases.

Quality of life - The SF-36

The SF- 36 consists of an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. It is useful in a variety of clinical settings since the questions are not disease-specific. The SF-36 showed one not significant difference compared to the standard group: bodily pain was the only level not significantly lower in our patient-group compared to the control-group. This fits with the assumption that chronic heart failure should not contribute to bodily pain. The reductions in physical role and mental health scores in the patients were modest (close to being statistically significant).

The individual SF-36 results showed large variations. There were patients with all scores between 0 and 35 and on the other hand several patients with scores between 50 and 100. This was related to their NYHA-class. But emotional role and social functioning scores were not at all related to the NYHA-class. This can reflect that a big part of quality of life is also dependent on the people surrounding the patients and their own attitude to life.

We compared the physical functioning score and the estimated NYHA-class and got a correlation coefficient of 0.67 (0.72 Spearman Correlation) with a significant p-value. This reflects that the NYHA-evaluation says something about the ability to perform physical activities and that the

physical functioning score can predict the NYHA-class.

We compared the physical role with the estimated NYHA-class and we did not get a significant correlation. Although the best and the worst scores seem to show a correlation, those with NYHA-classes of 2 and 3 had a large variation in their SF-score. This may be due to other factors of limitations, like rheumatologic diseases.

In our study the group consists of very sick people. Without surgery they would not survive for long[20]. There has been a study showing that patients with impaired LV function and ischemic mitral insufficiency were unlikely to demonstrate a significant improvement in quality of life at 3 months follow up[19]. Despite this MVR can be performed with low perioperative morbidity and mortality even in patients with advanced heart failure[20].

Limitations

- *Lack of preoperative SF-36 results*

Our study was to a large extent limited to follow-up. We have several preoperative medical data of the patients, but lack the SF-36 results preoperatively. Despite this, we would presume that a preoperative SF-36 evaluation would show poor quality of life. Our data was compared to the Urban Jewish population between 45 and 75[8]. In a lot of countries they have a national registry with the scores of the SF-36 among the general population at different ages. This does not exist in Israel, so our data are the closest we came to this kind of general information about the countries citizens. This is not optimal, but it says something about the difference between our group of relative sick people and the general population. The hospital is now starting to assess the SF-36- score of patients preoperatively, and in the future it will be possible to do another study with more complete data. There are few patients every year, and therefore the data of these is still not ready at the endpoint of this study.

- *The way the questions were asked.*

The Israeli population is very mixed. The language background of the patients was Hebrew, English, Arabic and Russian. We had the translation of the questionnaire into English and Hebrew, but lacked the translations to Arabic and Russian. Although we may assume that the persons translating the questions to the patients were competent, there is a possibility of misunderstanding and misinterpretation.

The patients who answered the SF-36 at the hospital, had someone familiar with the questionnaire was sitting beside them, explaining difficulties if necessary. This may be a different setting from the patients answering at home, who did not have this extra help.

Due to the limited number of patients, we (also) had a statistical power problem with the comparisons. We have the preoperative-data, and risk-factors, but the SF-36 questionnaire was only initiated at the point of the late follow up of this patient group.

Other limitations

- *Gathering of NYHA-data*

The NYHA-functional class of the patients were evaluated preoperatively and during follow up. It is based on several questions about the patient's physical abilities. Although these questions are standardized, there will always be a component of subjectivity in the evaluation of the answers.

Mortality was 39 % or 16 patients out of 41 at the time of our investigation. The prognosis of patients with chronic heart failure has changed very much the last 20 years. Some of the most important reasons for that is newer and better medical treatment on the one hand, and on the other hand improvement of surgical technique. The reports on the prognosis of patients with NYHA-functional class III and IV without surgery, data are from patients offered yesterday's medical

treatment. Today, drug and device treatment for severe heart failure has improved considerably, and therefore we cannot be absolutely sure that the results are still valid. However, it is reasonable to assume that without surgical intervention the life expectancy of these patients are still very poor.

Operation?

Despite the lack of prospective, randomized studies on the topic, there is large evidence supporting the superiority of mitral valve repair over replacement[6, 7, 21]. Lately a discussion about the method of treatment of this group of patients has started[22].

CONCLUSION

The primary aim of mitral valve surgery and the medical care around it is to improve survival as well as the overall functional capacity and health of patients. Despite that in the survivors, the LVEDD did not change significantly; the NYHA-class did improve, and also the symptoms. Our results of quality of life may be useful during the assessment and counselling of patients preoperatively. The atrial fibrillation and renal failure as risk factor show a significant correlation to death as end-point and can be used as the preoperative evaluation of patients before elected for operation. Although mortality is high, the perioperative mortality is low and there are patients who are in good mental and physical state at long-time follow-up. This study does not provide much new data, but confirms previous findings.

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